



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------------------|---------------------|------------------|
| 10/624,243 | 07/22/2003 | Corinne Elizabeth Augelli-Szafran | 16915 (PC20502A) | 7557 |
| 28880 | 7590 | 04/25/2006 | EXAMINER | |
| WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD ANN ARBOR, MI 48105 | | | OLSON, ERIC | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1623 | |

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|------------------------|------------------------|
| | 10/624,243 | AUGELLI-SZAFRAN ET AL. |
| Examiner | Eric S. Olson | Art Unit |
| | | 1623 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 June 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-12 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____ .
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

Detailed Action

This application claims benefit of provisional application 60/397901, filed July 23, 2002. Claims 1-12 are pending in this application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to a method of treating Alzheimer's disease, classified in class 514, subclass 376.
- II. Claims 5-8, drawn to a method of imaging amyloid deposits in a patient, classified in class 514, subclass 376.
- III. Claims 9-12, drawn to a compound according to formula I, classified in class 548, subclass 228.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions of groups I and II have a materially different design, mode of operation, function, and effect. The invention according to group I is directed to a method of treating Alzheimer's disease, while the invention of group II is directed to a method of imaging amyloid deposits in a patient. The therapeutic method of group I can be used independently of

the diagnostic method of group II, to treat patients diagnosed according to another therapeutic method. Similarly, the invention of group II could be used independently of the therapeutic method of group I, for example to study the deposition of amyloid deposits in the brain of an animal subject. A search for therapeutic methods involving a particular chemical compound is unlikely to discover references in the literature to a method of imaging utilizing said compound, and a reference anticipating or rendering obvious a method of imaging will not thereby anticipate or render obvious a therapeutic method.

Because these inventions are distinct for the reasons given above and the search required or group I is not required for group II, restriction for examination purposes as indicated is proper.

Invention III is related to inventions I and II as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the therapeutic method of group I could be practiced with a different therapeutic compound such as Dozeprine, and the method of imaging amyloid plaques could be practiced with a radiolabeled antibody or amyloid-binding polypeptide.

The search field for a compound is non-coextensive with the search field for a method of treating a patient employing the same composition. A reference to the

composition herein would not necessarily be a reference to the method of treatment herein under 35 USC 103 because a search indicating the process or method is novel or unobvious would not extend to a holding that the product is novel or unobvious whereas a search indicating that the product is known or would have been obvious would not extend to a holding that the process or method is known and would have been obvious. Note that the search is not limited to patent files. Thus an undue burden on the Office is seen for the search of all inventions herein, as discussed in the Requirement for Restriction above.

Because these inventions are distinct for the reasons given above and the search required for Groups I and II is not required for Group III, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised

that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because the above restriction requirement is complex, a telephone call to applicant's agent to request an oral election was not made. (See MPEP 812.01)

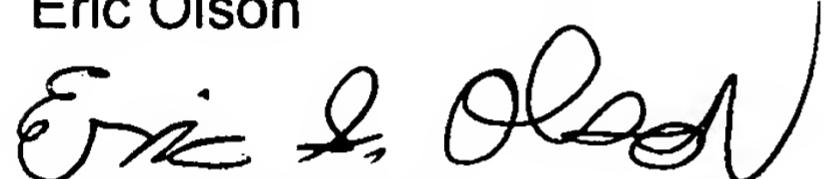
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday through Friday from 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eric Olson



Patent Examiner
AU 1623
4/17/06

Anna Jiang



4/19/06

Supervisory Patent Examiner
AU 1623